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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,641	05/03/2002	Dac Gun Kim	6181/OK439	3102
7590 02/23/2004				
S Peter Ludwig		EXAMINER		
Darby & Darby		WHITEMAN, BRIAN A		
Post Office Box 5257		ART UNIT PAPER NUMBER		
New York, NY 10150-5257		1635		

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,641

Applicant(s)

KIM ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/28/02</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Non-Final Rejection

Claims 1-10 are pending examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Korea on 7/31/00. It is noted, however, that applicant has not filed a certified copy of the application Republic of Korea 2000/44142 as required by 35 U.S.C. 119(b).

There is no evidence of record that the International Bureau had received the priority document.

Information Disclosure Statement

The international search report has been considered.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The first sheet of the published application is not considered an abstract on a separate sheet.

Claim Objections

Claims 1, 5, and 7 are objected to because of the following informalities: the phrase "P972 gene" in claims 1, 5, and 7 is grammatically improper. Suggest amending the phrase to recite -- a P972 gene --. Appropriate correction is required.

Claims 2-4, 6, and 8-10 are also objected to because the claims are dependent on claims 1, 5, or 7.

Claim 6 is objected to because of the following informalities: the phrase is "an adenovirus of claim 5" is a grammatically improper phrase for a dependent claim. Suggest amending the phrase to recite -- the adenovirus vector of claim 5 --.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "a promoter operably linked to the same" in claims 1, 5, and 7 is a relative term, which renders the claims indefinite. The term "a promoter operably linked to the same" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

invention. The claims do not define the metes and bounds of the term because it is unclear what the promoter is being linked to.

Claims 2, 3, 4, 6, and 8-10 are indefinite because the claims depend from claims 1, 5, and 7.

Claim Rejections - 35 USC § 102

The expression vector in Claims 2, 3, 8 and 9 recites an intended use “for the treatment of cancer.” The intended use of the expression vector in the instant claims for the treatment of cancer does not have patentable weight for prior art rejections. An intended use does not provide an alteration to the expression vector that distinguishes it from that taught in the art of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al. (Int. J. Oncol. 2001, April, 18: 749-57). Zhang teaches inserting the murine CR6 (aka P972) cDNA into a mammalian expression system (page 750, Materials and Methods). Zhang further teaches transfecting a cell line with the mammalian expression system comprising the murine CR6 cDNA (page 750 and 751).

The instant specification teaches that P972 is also referred to as Gadd45-gamma, CR6 or OIG37 (see abstract).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama et al., (The Journal of Biological Chemistry, 274:24766-24772, 1999, cited on the 1449). Nakayama teaches a retrovirus carrying OIG37 (aka P972) cDNA and transfecting a cell line with the retrovirus (page 24767, experimental procedure).

The instant specification teaches that P972 is also referred to as Gadd45-gamma, CR6 or OIG37 (see abstract).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al. (US 6,027,914). Smith teaches a vector and a host cell transformed with the vector having a polynucleotide sequence encoding a CR6 (aka P972) polypeptide (column 131, lines 50-58). Smith further teaches using a suitable mammalian vector, including an adenoviral vector comprising a polynucleotide sequence encoding a CR6 polypeptide (column 10, line 35- column 11, line 62 and column 15, lines 5-56).

The instant specification teaches that P972 is also referred to as Gadd45-gamma, CR6 or OIG37 (see abstract).

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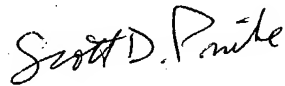
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER